UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Rockwell Medical, Inc. Securities Litigation	Case No. 16-cv-01691 (RJS) **SECOND AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Lead Plaintiffs Dmitriy Chatskiy, Douglas Benkowski and Earl McCrary ("Plaintiffs"), individually and on behalf of all other persons similarly situated, by Plaintiffs' undersigned attorneys, for Plaintiffs' complaint against Defendants (defined below), allege the following based upon personal knowledge as to Plaintiffs and Plaintiffs' own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiffs' attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Rockwell Medical, Inc. ("Rockwell Medical" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased Rockwell Medical publicly traded common stock and/or call options and/or those who sold put options between November 20, 2014 and February 29, 2016, both dates inclusive (the "Class Period"). Plaintiffs seek to recover compensable damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections

10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its officers and/or directors.

2. Rockwell Medical is a biopharmaceutical company that targets end-stage renal disease and chronic kidney disease with products and services for the treatment of iron deficiency, secondary hyperparathyroidism, and hemodialysis. According to the Company's Form 10-K for the year 2015, Triferic – the Company's "lead branded drug" – is an iron compound that is delivered to hemodialysis patients via dialysate, replacing the ongoing iron loss that occurs during dialysis treatment.

3. On March 24, 2014, the Company issued a press release announcing the submission of a New Drug Application (the "2014 NDA") to the U.S. Food and Drug Administration ("FDA") seeking approval for the marketing and sale of Triferic. The 2014 NDA was specifically for a liquid formulation of Triferic. According to the Company, "[o]nce in the dialysate, Triferic crosses the dialyzer membrane and enters the blood where it immediately binds to apo-transferrin and is taken to the bone marrow, similar to how dietary iron is processed in the human body. In completed clinical trials to date," the Company continued, "Triferic has demonstrated that it can safely and effectively deliver sufficient iron to the bone marrow, maintain hemoglobin and not increase iron stores (ferritin), while significantly reducing ESA dose."[1]

[1] As the Company stated in its Annual Report on Form 10-K for the period ended December 31, 2014 ("2014 10-K"), "Triferic™ could significantly reduce the need for erythropoiesis stimulating agents (""ESA"). ESA drugs are the most expensive drugs used in dialysis." ESA drugs are for "the treatment of anemia associated with chronic kidney disease "to elevate or maintain the red blood cell level . . . and to decrease the need for transfusions." Ellis F. Unger, M.D., Aliza M. Thompson, M.D., Melanie J. Blank, M.D., and Robert Temple, M.D., *Erythropoiesis-Stimulating Agents — Time for a Reevaluation* 362 New Eng. J. Med. 2010 189 (2010).

4. Unbeknownst to investors, as Defendants would later admit, prior to the submission of the 2014 NDA for liquid Triferic, the Company had "created a more efficient and more cost-effective way to package Triferic." The powder form of Triferic (packaged in packets similar to sugar packets) offered a number of benefits over the liquid form for both Rockwell and its customers, including lower production costs, greatly decreased susceptibility to contamination during production, cheaper cost of goods, cheaper shipping, lower storage costs, and a longer shelf-life. This powder formulation also required its own NDA – which was not ready at the time the Company submitted the 2014 NDA for the liquid form of Triferic. Still, eager to excite the investing market, the Company charged ahead with the liquid formulation – all the while intending the (not-yet-approved) powder formulation of Triferic to serve as the primary product offering of Triferic, as the powder form was more commercially viable.

5. On January 26, 2015, the Company issued a press release announcing that "the U.S. Food & Drug Administration (FDA) has approved its drug Triferic for commercial sale as an iron replacement product to maintain hemoglobin in adult patients with hemodialysis dependent chronic kidney disease." The approved formulation of Triferic was liquid ampoule. According to the Company, "Triferic's unique ability to be delivered via dialysate and to deliver iron without increasing iron stores strengthens its potential to become the market leading iron therapy treatment for hemodialysis patients. We view today's FDA decision as a major development both for Rockwell and for the entire hemodialysis patient population," the Company continued, "who now have a significantly better treatment option for addressing their iron losses." The Company concluded, "We are highly confident in executing a successful commercial launch and penetrating the market. We thank the patients and physicians who participated in our clinical program as well as our highly skilled team of clinical, manufacturing and regulatory professionals."

6. Defendants further portrayed Triferic as "a paradigm shift in the treatment of anemia." According to the Company's Chief Medical Officer, Dr. Raymond Pratt, "Importantly, Triferic is the first product that can safely allow dialysis patients to maintain target hemoglobin without the need for IV iron." Dr. Pratt further stated that "[d]ata suggests that we have been overloading our dialysis patients with IV iron, and this is an increasing concern to the hemodialysis community. Triferic offers a more physiologic way to deliver and maintain iron balance in hemodialysis patients."

7. The "paradigm shift" of which Dr. Pratt spoke, however, was far from evident. For example, in a September 3, 2015 "editorial collaboration" between the National Kidney Foundation and Medscape, Dr. Jeffrey S. Berns,[2] editor-in-chief of the Medscape Nephrology wrote a commentary titled *Triferic: Any Better than IV Iron for Dialysis Patients?* Dr. Berns noted that "about 80% of patients received IV Iron at some time over a 3 month period. A lot of IV iron is being given to our dialysis patients." Dr. Berns summarized several published studies of Triferic, concluding that "[t]here is no question that Triferic provides more iron than no iron or standard dialysate, is it as good or better than IV iron? Is it safer? Does it reduce the need for transfusions compared with IV iron? Is there an improvement in patient outcomes? We really don't know." Dr. Berns continued that:

> One concern is that the use of dialysate iron may be all or none. In other words, you can't give a little bit one month and a little bit more the next month. A fixed amount is delivered across the dialyzer. The dose can't be varied, as far as I know. It also makes me inherently nervous to have staff adding things to dialysate, although it makes me nervous when anything is given intravenously in a dialysis unit. We will have to see whether any safety issues arise over the long

[2] Dr. Berns is Associate Chief, Renal Electrolyte and Hypertension, Associate Dean for Graduate Medical Education, Director, Renal Fellowship Program and Professor of Medicine at the Hospital of the University of Pennsylvania and the Presbyterian Medical Center of Philadelphia. Dr. Berns is also Chairperson of the National Kidney Foundation Scientific Advisory Board.

> term with the use of this form of iron delivery. ***Cost also may be an issue***. (Emphasis added).

8. In addition to the safety and efficacy equivalence of Triferic to IV iron, the Company had not convinced the FDA to grant it permission to label the product to encourage the reduction in ESA usage and the accompanying cost savings that reduction would yield. As such, the pricing of Triferic was critical to its launch. Having tied its profitability to the Company's ability to launch Triferic, Defendants could not disclose the existence of the more cost effective powder version of Triferic, for which the Company had yet to receive FDA approval. To discuss the powder version of Triferic would have forced Defendants to disclose to the market the pricing problem the Company faced with the liquid version of the drug. In turn, talk of a commercial launch would be folly as dialysis centers and investors awaited a more cost-effective Triferic that the FDA had not yet even approved. Had they disclosed the existence of the powder and their intention that it replace the liquid version, therefore, Defendants would have been unable to claim that profitability was imminent after launch.

9. On June 25, 2015, the Company secretly submitted a separate NDA to the FDA to seek approval for Triferic in the powder packet formulation (the "2015 NDA"), which would serve as the primary product offering for Triferic once it was approved. Defendants neither disclosed the existence of Triferic in powder form, nor the Company's submission of the NDA for its approval.

10. On September 9, 2015, the Company issued a press release announcing the commercial launch of Triferic and touting it as "the only FDA approved iron product indicated to replace iron and maintain hemoglobin in hemodialysis patients in the United States." The Company also stated that "Triferic benefits patients, nurses, doctors and healthcare providers and

we are very motivated to commercialize it. We believe Triferic will become the standard of care in iron replacement for dialysis patients."

11. On November 9, 2015, the Company held its third quarter 2015 financial results conference call (the "Q3 2015 Earnings Call") with securities analysts and investors. With regards to Triferic, Defendant Chioini stated during the Q3 2015 Earnings Call that the Company had "just signed a supply contract with one of the four largest dialysis providers."

12. Against this backdrop, throughout the Class Period, Defendants failed to disclose that the powder packet formulation of Triferic, which was not yet FDA-approved in 2015, would be the primary product offering for Triferic because it was more likely to be commercially viable given its lower cost to manufacture and transport and lower cost for end users.

13. On February 29, 2016, the Company held its fourth quarter 2015 financial results conference call (the "Q4 2015 Earnings Call") with securities analysts and investors. During the 4Q 2015 Earnings Call, Defendant Thomas Klema revealed that "our net sales of Triferic were immaterial for 2015."

14. Also during the Q4 2015 Earnings Call, attempting to assuage investors' fears and rebuild confidence in the Company and Triferic, Defendant Chioini revealed for the first time that the Company previously submitted a separate NDA to the FDA in 2015 "to package Triferic as a powder in a packet." Defendant Chioini praised the powder packet form of the drug as "more efficient and more cost-effective." Defendant Chioini further said that once approved, "[t]he powder packet will be commercially available immediately thereafter, and it will be the primary product offering [of Triferic]."

15. On this news, shares of Rockwell Medical fell $3.29 per share, or more than 34%, to close at $6.31 on March 1, 2016, on unusually heavy trading volume.

16. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

17. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and §78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

18. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

19. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as a significant portion of the Defendants' actions, and the subsequent damages, took place within this District.

20. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

21. Lead Plaintiff Dmitriy Chatskiy purchased Rockwell Medical common stock at artificially inflated prices during the Class Period and has been damaged thereby. His PSLRA certification was previously filed with the Court and is incorporated by reference herein.

22. Lead Plaintiff Douglas Benkowski purchased Rockwell Medical common stock at artificially inflated prices during the Class Period and has been damaged thereby. His PSLRA certification was previously filed with the Court and is incorporated by reference herein.

23. Lead Plaintiff Earl McCrary purchased Rockwell Medical common stock at artificially inflated prices during the Class Period and has been damaged thereby. His PSLRA certification was previously filed with the Court and is incorporated by reference herein.

24. Defendant Rockwell Medical operates as an integrated biopharmaceutical company in the United States and internationally, and offers products and services for the treatment of end-stage renal disease, chronic kidney disease, iron deficiency, secondary hyperparathyroidism, and hemodialysis. Rockwell Medical is incorporated in Michigan with principal executive offices located at 30142 Wixom Road Wixom, Michigan 48393. Rockwell Medical's securities trade on NASDAQ under the ticker symbol "RMTI."

25. Defendant Robert L. Chioini ("Chioini") has been the President, Chief Executive Officer ("CEO"), and Director (Principal Executive Officer) of Rockwell Medical throughout the Class Period.

26. Defendant Thomas E. Klema ("Klema") has been the Vice President of Finance, Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer) throughout the Class Period.

27. Defendants Chioini and Klema are sometimes referred to herein as the "Individual Defendants."

28. Defendant Rockwell Medical and the Individual Defendants are referred to herein, collectively, as the "Defendants."

29. Each of the Individual Defendants:

(a) directly participated in the management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was privy to confidential proprietary information concerning the Company and its business and operations;

(d) was involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(e) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and

(f) approved or ratified these statements in violation of the federal securities laws.

30. As officers, directors, and controlling persons of a publicly-held company whose securities are and were registered with the SEC pursuant to the Exchange Act, and was traded on NASDAQ and governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to disseminate accurate and truthful information promptly with respect to the Company's business prospects and operations, and to correct any previously-issued statements that had become materially misleading or untrue to allow the market price of the Company's publicly-traded stock to reflect truthful and accurate information.

31. Rockwell Medical is liable for the acts of the Individual Defendants and its employees under the doctrine of respondeat superior and common law principles of agency as all of the wrongful acts complained of herein were carried out within the scope of their employment with authorization.

32. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to Rockwell Medical under respondeat superior and agency principles.

SUBSTANTIVE ALLEGATIONS

Background

Triferic

33. Blood loss occurs during the course of dialysis treatment, which results in the loss of iron. Triferic is an iron replacement product that replaces iron and maintains hemoglobin concentration in hemodialysis patients.

34. On March 24, 2014, the Company issued a press release announcing its submission of the NDA for Triferic to the FDA. The 2014 NDA sought approval for the marketing and sale of Triferic in a liquid formulation.

35. In announcing the submission of the 2014 NDA for Triferic to the FDA, the Company touted that "Triferic is expected to address an estimated $600M U.S. market."

36. Unbeknownst to the investors, however, prior to the 2014 NDA submission, the Company had simultaneously developed a powder packet formulation of Triferic, which it intended to be the primary product offering for Triferic because it was far more likely to be commercially viable given its lower cost to manufacture and transport and lower cost for end users and would be the subject of its own NDA filed in June 2015.

37. In the 2014 10-K, the Company explained:

> To currently address iron deficiency, patients receive intravenous (IV) iron and ESA. ESA is an artificial hormone that acts in the bone marrow, together with iron, to increase the production of red blood cells, which carry oxygen throughout the body to nourish tissues and sustain life. Hemoglobin, an important constituent of red blood cells, is composed largely of iron and protein.
>
> Current clinical practice for iron therapy for CKD-HD patients is provided mainly with IV iron compounds, which are approved for iron repletion, not maintenance. IV iron is encased by a carbohydrate shell to prevent free-iron from circulating in the bloodstream. Due to the carbohydrate shell, IV iron is taken up by the reticuloendothelial system and deposited primarily in the liver,

rather than directly into blood plasma where it would be carried to the bone marrow. An increase in inflammation during dosing, coupled with chronic inflammation found in ESRD patients, causes a peptide called hepcidin to mobilize and block the majority of IV iron from leaving the liver, increasing iron stores. This functional iron deficiency can reduce the effectiveness of ESA treatments. The carbohydrate moiety in IV iron compounds is also believed to be responsible for the anaphylactic reactions that may occur.

Triferic™ is distinctly different from IV iron compounds. Triferic™ is an iron salt and contains no carbohydrate. Triferic™ enters the bloodstream through dialysate and immediately binds to transferrin (the body's natural binding site for iron) and is carried directly to the bone marrow for the formation of new red blood cells. Triferic™'s efficient binding action is similar to how a healthy human body processes dietary iron when received via food. Triferic™ effectively delivers iron and maintains hemoglobin without increasing iron stores. Triferic™ has demonstrated an excellent safety profile in its Phase 3 clinical program and has not been attributed to any anaphylaxis in over 100,000 administrations.

The PRIME study demonstrated that this more direct method of iron delivery is able to significantly reduce ESA treatment. In this study, Triferic™ patients used 35% less ESA than placebo patients and ESA hyporesponsive patients used 74% less ESA (see PRIME study design and results below).

ESA is administered intravenously during dialysis treatments to help maintain hemoglobin levels. Iron supplementation is required to ensure good therapeutic response from ESA treatments. Most dialysis patients receive ESA therapy coupled with iron therapy in order to maintain hemoglobin levels and to achieve the full benefit of ESA treatments. ESAs are very expensive drugs and are known to have serious risks associated with their dosing to dialysis patients.

Triferic™, in place of IV iron, has shown it can effectively deliver iron and maintain hemoglobin without increasing iron stores, and the PRIME study has shown Triferic™ can lower ESA use. Triferic™ additionally lowers IV iron drug administration cost to dialysis providers. Along with the elimination of the needle and syringe normally used for IV iron administration, a nurse will not have to administer individual injections of IV iron, thereby reducing the amount of time required for IV iron administration, permitting nursing time to be redeployed to other patient care activities.

During 2013, Rockwell successfully completed its two pivotal Phase 3 efficacy trials, called CRUISE-1 and CRUISE-2, for Triferic™. The CRUISE studies were identical single-blind, placebo controlled, parallel group, multi-center studies comparing Triferic™ delivered via hemodialysate concentrate to placebo with standard hemodialysate concentrate with 600 subjects split evenly between the two studies and treatment arms. Both of the CRUISE studies successfully met their primary endpoint, demonstrating a statistically significant mean change in hemoglobin from baseline to End-of-Treatment. Triferic™ also met key secondary endpoints including maintenance of hemoglobin, maintenance of reticulocyte hemoglobin and increase in serum iron pre-to-post treatment without an increase in ferritin.

A third Phase 3 trial, called the PRIME study demonstrated that ***Triferic™ significantly reduces the need for ESA during dialysis***. The PRIME study was a nine-month, prospective, randomized, placebo-controlled, double-blinded, multi-center study in the United States that randomized patients equally to dialysate containing Triferic™-iron versus conventional dialysate. A total of 103 patients received blinded study drug (52 Triferic™, 51 Placebo). Both groups were able to have ESA doses titrated to keep hemoglobin levels within the target range, and both groups could receive IV iron if they developed absolute iron deficiency. Both groups successfully kept their hemoglobin concentrations within the target range, but the Triferic™ patients used 35% less ESA to do so than placebo patients. ESA hyporesponsive patients—those on more than 13,000 units of epoetin per week—needed 74% less ESA in the Triferic™ group compared to the placebo group. Hypo-responsive patients are generally estimated to represent approximately 20% of the dialysis population. According to Amgen Inc., which sells the vast majority of ESA drugs in the dialysis market, over $2.8 billion was spent on Amgen's ESA drugs in 2014 in the United States and we estimate that approximately $2.3 billion of Amgen's ESA sales were to the hemodialysis market.

In January 2014, we completed our long term safety study for Triferic™ which was a prospective, randomized, double-blinded, placebo-controlled, crossover, multicenter, multinational, Phase 3 study with an enrollment of 718 CKD-HD patients in the United States and Canada. This large-scale long term safety study, coupled with the successful Phase 3 CRUISE studies, dosed over 100,000 Triferic™ administrations and demonstrated a safety profile similar to placebo patients.

> We plan to commercialize Triferic™ in 2015 using our current sales and marketing infrastructure. We intend to out-license the rights to Triferic™ for commercial development in markets outside of the United States. (Emphasis added).

38. Thus, Defendants tied cost savings from the liquid form of Triferic directly to costs savings the use of Triferic would yield in reduced ESA use.

39. The medical community, however, was ambivalent at best about Triferic. For example, on September 3, 2015, Dr. Jeffrey S. Berns, Professor of Medicine at the Hospital of the University of Pennsylvania and Chairperson of the National Kidney Foundation Scientific Advisory Board, delivered a video for Medscape, finding that no science had shown that Triferic was safer or more effective than IV iron. While Dr. Berns concluded that "Triferic provides more iron than no iron or standard dialysate," the studies to date had left the medical community wholly unsure about whether Triferic is better or safer than IV iron – no resolution on whether Triferic afforded "an improvement in patient outcome. We don't really know." Among the specific concerns Dr. Berns articulated was the inability to vary dosages of Triferic, something one can do with IV iron. Dr. Berns concluded to that "cost also may be an issue." While he did not wholly dismiss Triferic, Dr. Berns stated, "it would be interesting, and important, to see additional head-to-head comparisons between ferric pyrophosphate citrate [(Triferic)], and iron sucrose [(IV iron)]."

40. Sell side securities analysts understood this. For example, on August 5, 2015, Jonathan Aschoff of Brean Capital LLC wrote:

> Rockwell still plans to launch Triferic in mid-2015, but has not yet determined pricing or started pilot programs. We expect dismal commercial uptake for Triferic and reiterate our Sell rating and $4 TP. Most dialysis centers currently have IV iron in their protocol, and although some care providers participated in Rockwell's trials, the dialysis centers will need to conduct pilot studies to understand how Triferic fits into the dialysis process and accordingly tweak

their current protocol to use Triferic, thereby slowing its adoption. Recall that Triferic was tested in a Phase 3 trial against a control group that has nothing to do with a dialysis center's activities and thus has yielded data that are both uninterpretable and uninformative to care givers. Triferic is just a substitute for IV iron and is not justified to command premium pricing to IV iron. ***As an IV drug without ESA sparing benefits, Triferic will not improve dialysis center margins, and dialysis centers have already shown that their choice of drugs under bundled reimbursement is in large part driven by economics***. Rockwell still plans to launch generic Calcitriol also in mid-2015 (also not launched yet). We believe that generic IV Calcitriol will not add meaningful value to Rockwell, since IV Calcitriol will be subject to bundled reimbursement and that oral Calcitriol has been approved for many years, is inexpensive and widely available, and that there are several far larger competitors.

Triferic update. Rockwell plans to launch Triferic in mid-2015, but has not yet determined pricing or started pilot programs. We expect dismal commercial uptake for Triferic and reiterate our Sell rating and $4 TP. Most dialysis centers currently have IV iron in their protocol, and although some care providers participated in Rockwell's trials, dialysis centers will need to conduct pilot studies to understand how Triferic fits into the dialysis process and accordingly tweak their current protocol to use Triferic, thereby slowing its adoption. Recall that Triferic was tested in a Phase 3 trial against a control group that has nothing to do with a dialysis center's activities and thus has yielded data that are both uninterpretable and uninformative to care givers. ***We also believe that without ESA sparing effects on the label, Triferic is just a substitute for IV iron and is not justified to command premium pricing to IV iron. As an IV drug without ESA sparing benefits, Triferic will not improve dialysis center margins, and dialysis centers have already shown that their choice of drugs under bundled reimbursement is in large part driven by economics***. Unlike with Keryx's (KERX $7.34, Buy $26 TP) Auryxia, Rockwell cannot explain away a slow launch by saying that a critical mass of Medicare payers need to first be on board, as Triferic will be bought by dialysis centers. As for the FDA approved generic drug Calcitriol, Rockwell still plans to launch it in mid-2015 around the same time as Triferic. We believe that generic IV Calcitriol will not add meaningful value to Rockwell, since IV Calcitriol will be subject to bundled reimbursement and that oral Calcitriol has been approved for many years, is inexpensive and widely available, and that there are several far larger competitors, some of which have both doses of generic IV Calcitriol. (Emphasis added).

41. Given that Triferic had no ESA-sparing effects on the label, therefore, it was not superior to then existing treatments for iron deficiency in dialysis patients. Even equivalent efficacy to IV iron, therefore, cost was not an issue, it was the only issue to the successful commercialization of Triferic. If it cost less than IV iron, dialysis providers could add it to the dialysate bundle and save money. If not, the Company would face an uphill battle to commercialize Triferic. To commercialize Triferic successfully – something they claimed they were doing in the fall of 2015 – the very cost of the product was critical. The problem for the Company, however, was that while it had a more cost-effective version of Triferic in the pipeline, it had not yet achieved FDA approval for the powder version of the drug. Thus, the Company risked the commercialization and its efforts to prompt dialysis centers to incorporate the product for the mere promise of a more cost effective version. If the Company announced the NDA for the powder version, it risked all efforts to commercialize Triferic for a version that the FDA might not approve.

42. Short of Defendants disclosing that they had submitted a separate and additional NDA for Triferic in powder form, investors had no way to discover that fact. The mere submission of an NDA to the FDA is not publicized in any way by the FDA. In fact, prior to drug approval, federal regulations prohibit the FDA from publicly disclosing the submission of applications unless the drug sponsor does so first. *See* 21 C.F.R. § 312.130(a) ("The existence of an investigational new drug application will not be disclosed by FDA unless it has previously been publicly disclosed or acknowledged"); 21 C.F.R. § 314.430(b) ("FDA will not publicly disclose the existence of an application or abbreviated application before an approval letter is sent to the applicant under 314.105 or tentative approval letter is sent to the applicant under 314.107, unless

the existence of the application or abbreviated application has been previously publicly disclosed or acknowledged").

Materially False and Misleading Statements Issued During the Period

43. The Class Period Begins on November 20, 2014. On that day the Company filed a Prospectus Supplement (the "Prospectus") with the SEC pursuant to Rule 424(b)(5). In the Prospectus the Company touted the eminent success of its Triferic drug candidate. The Company stated in relevant part:

> Our lead investigational drug, Triferic™, also known as Soluble Ferric Pyrophosphate or SFP, delivers iron to the bone marrow in a non-invasive, physiologic manner to hemodialysis patients via dialysate during their regular dialysis treatment***. We submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, in the first quarter of 2014 seeking marketing approval of Triferic™.*** We also plan to seek foreign market approval for this product and/or out-license the technology to a company who will seek market approval in foreign markets.
>
> * * *
>
> ***Triferic™ has a Prescription Drug User Fee Act, or PDUFA, date of January 24, 2015. The PDUFA date is the goal date for the FDA to complete its review of the NDA.*** There can be no assurance that the FDA will complete its review of the NDA by this date. When and if we obtain FDA approval, we intend to market Triferic™. We cannot, however, give any assurance that Triferic™ will be approved by the FDA or, if approved, what will be included in the approved label or whether Triferic™ once launched will be successfully marketed.
>
> * * *
>
> We intend to become a leading biopharmaceutical company focused primarily on renal indications, while leveraging our operating business infrastructure to market and sell approved drugs commercially. The following are the key elements of our business strategy:
>
> *Obtain Regulatory Approval of our Lead Drug Candidate Triferic™ for the Treatment of Iron Deficiency in Hemodialysis Patients.*

> ***We are seeking and intend to obtain FDA regulatory approval to market Triferic™ commercially.*** Based on a report from a manufacturer of intravenous iron products from 2012 and industry estimates, we believe the market size in the United States for IV iron therapy for ESRD patients is between approximately $300 and $600 million per year. Through the Distribution Agreement with Baxter, we expect to sell to and service a significant number of dialysis providers in the United States and intend to market Triferic™ to those dialysis providers. (Emphasis added).

44. On January 26, 2015, the Company issued a press release announcing that the FDA approved Triferic for commercial sale. In the press release, Defendant Chioini touted Triferic's ability to become the market-leading therapy for hemodialysis patients combating chronic kidney disease and professed their confidence in a successful commercial launch of Triferic, stating in relevant part:

> "We are extremely pleased with the FDA approval of Triferic. It is the first drug approved to replace ongoing iron losses and to maintain hemoglobin levels in hemodialysis patients." […] "Triferic's unique ability to be delivered via dialysate and to deliver iron without increasing iron stores strengthens its potential to become the market-leading iron therapy treatment for hemodialysis patients. We view today's FDA decision as a major development both for Rockwell and for the entire hemodialysis patient population who now have a significantly better treatment option for addressing their iron losses. ***We are highly confident in executing a successful commercial launch and penetrating the market***. We thank the patients and physicians who participated in our clinical program as well as our highly skilled team of clinical, manufacturing and regulatory professionals." (Emphasis added).

45. On February 26, 2015, the Company held its fourth quarter 2014 financial results conference call (the "Q4 2014 Earnings Call") with securities analysts and investors. During the Q4 2014 Earnings Call, Defendant Chioini stated the following with regards to the anticipated commercial launch of Triferic:

> We are starting 2015 in a very strong financial position to execute our strategic initiatives and to achieve our goals. ***Our strong financial position will enable us to launch two drugs this year***

> ***Triferic*** and Calcitriol, which includes spending for manufacturing API, packaging finished product, inventory, marketing and sales among other things.
>
> * * *
>
> ***We currently estimate launching Calcitriol near the end of the second quarter possibly at the same time we estimate launching Triferic***. Calcitriol and Triferic are two of the big three injectable drugs used in dialysis, the third being Amgen's Epogen. We anticipate solid commercial success of Calcitriol and we will provide you further updates as we progress.
>
> * * *
>
> ***Our goal is to launch Triferic commercially in approximately four to five months.*** We have been working diligently on numerous prelaunch tasks and we will continue to do so.
>
> We already have the infrastructure and customer relationships in place to sell Triferic successfully and we have considerable experience launching products into the renal market.
>
> Coupled with this drug's clinical and cost saving benefits, a favorable bundled reimbursement structure and a consolidated customer base, ***we have confidence that we will have great success selling Triferic in a dialysis market***. (Emphasis added).

46. During the Q4 2014 Earnings Call, Defendant Klema stated the following with regards to the anticipated commercial launch of Triferic:

> ***Our current cash resources are sufficient to commercially launch Triferic.*** Our launch spending is primarily related to working capital and marketing expenses for which our resources are ample. Our expected R&D spending in 2015 should not be significant in relation to our cash resources. Our balance sheet is very solid. We are well-positioned financially to execute our strategy. (Emphasis added).

47. During the Q4 2014 Earnings Call, Defendant Klema had the following exchange with an securities analyst concerning the Company's anticipated commercial launch of Triferic and Defendants' tying profitability directly to the launch of Triferic:

Jim Molloy

Great. Thank you. Then I know that the launch of Triferic and Calcitriol certainly should help turn the corner for you guys from losing money to making money. Internally do you have any thoughts on when that will happen? We have got our own projections out here, but what do you guys think?

Rob Chioini

I will let Tom handle that one. When do you think?

Tom Klema

Yes. ***I think once we have adequate inventory and we can launch. The company will be profitable shortly after that.*** It will not take much volume. The margins on these products will all be much better than our concentrated. (Emphasis added).

48. During the Q4 2014 Earnings Call, Defendant Chioini had the following exchange with an securities analyst concerning the Company's anticipated commercial launch of Triferic, in particular Defendants' focus on pricing the product to enable dialysis centers to save on each treatment:

Ling Wang

Thank you for taking my question. Rob, you mentioned that Triferic will launch will probably in about four to five months. Can you talk about the type of pre-launching activities you are doing right now?

Rob Chioini

Yes. Sure, Ling. It is very similar to most drug launches. I would imagine there is a lot of manufacturing activity around the API [Active Pharmaceutical Ingredient], ***getting enough of that made then getting it packaged***, you have got marketing activity, you have got building inventory activity, just stuff like that.

Ling Wang

Okay. My second question is that, I just wanted to get a sense of how you can utilize sort of the ESA sparing benefit, the data you got from the PRIME study, whatever in the public domain, in what way

> can you kind of utilize your data in your negotiation or is it just a matter for those dialysis centers to try on their own in order for them to try Triferic?
>
> **Rob Chioini**
>
> I will answer that in two ways. First, I am not going to discuss pricing. We have got several options and have some strategic go ways to price the product with providers that maximizes what each party wants. For us, the highest price possible and for them the lowest price possible.
>
> With that said, when we talk about ESA, Ling, the data out there really speaks for itself. In this industry, these providers, especially the big ones, but all of them are very focused on lowering cost per treatment.
>
> They have seen the Prime study, they have seen the 35% reduction overall, they have seen the 74% reduction in hyper responders, they have seen the CRUISE studies where when you look at the Triferic patients in the CRUISE studies, the great majority of them completed the study, the efficacy study, when their hemoglobins reached to 12. In that study, those patients once they entered the randomization phase or stage they were unable to have their ESA titrated, so you can imagine that had been the doctor been allowed to titrate that ESA as their hemoglobin approached to 12, the doctor would have lowered the ESA dose and the providers all have access to that data, they have seen that data and they will figure out ways on how to bring savings out of this drug above and beyond what we have shown.
>
> I am not concerned about trying to maximize ESA savings related to pricing the product. ***We will price the product with a couple of strategies that we have and our goal will be to price this high as we can and still save the customer cost per treatment or lower cost per treatment above and beyond that price***. (Emphasis added).

49. On May 7, 2015, the Company held its first quarter 2015 financial results conference call (the "Q1 2015 Earnings Call") with securities analysts and investors. During the Q1 2015 Earnings Call, Defendant Chioini stated the following with regard to the Company's anticipated commercial launch of Triferic:

> At the end of March, cash and investments were over $83 million with no debt. ***Our strong financial position provides us with ample resources to launch two drugs this year, Triferic*** and Calcitriol. Both require spending for manufacturing API, packaging finished product, inventory, marketing and sales. Based on our prelaunch activity to date, we estimate both drugs are on track for commercial launch in the July-August timeframe.
>
> ***For Triferic, we continue to work diligently on numerous prelaunch initiatives.*** Our activities at the moment are focused on the manufacturing and marketing aspects of the launch, which involves the making of API and the scale-up in CMO redundancy required as well as our communication with customers and our efforts to educate and to establish brand awareness around Triferic.
>
> * * *
>
> We are excited about the commercial potential for Triferic. ***Our confidence in our commercial launch is based on the strong efficacy and safety profile the drug has demonstrated*** as well as our own considerable experience and success in launching products into the renal market, a market where we have excellent long-standing relationships and the market that is very concentrated, where just nine customers control 85% of it.
>
> * * *
>
> ***We will continue to work hard to launch Triferic and Calcitriol as fast as possible.*** As you might imagine, there is enormous amount of work required securing at least two suppliers to produce the estimated demand for the market is a must. This redundancy is critical and we've achieved it with both drugs and we are moving closer to market launch. (Emphasis added).

50. During the Q1 2015 Earnings Call, Defendant Chioini had the following exchange with an securities analyst regarding the Company's anticipated commercial launch of Triferic:

> **Ling Wang**
>
> Sure. Thank you for taking my questions. So could you please talk about the main parameters that's impacting the timing for launch, whether you can get out June versus July, August?
>
> **Rob Chioini**

> Well, I don't know if I can point any specific parameters that will make the difference. There's a lot of activity. ***I think the best way to describe it is there's multiple things that are going on and they are all related and they all need to get done at one point and once they're all done then you can launch.***
>
> ***So as we look at -- as we try to estimate the launch, which is always difficult, we take all those factors into consideration.*** And really they are the ones that I mentioned in the call. The manufacturing of APIs, there is a lot of lab work involved, making sure that your suppliers are setup and their schedule -- they've scheduled in your product beyond post-launch. There's just a lot to it. Most of it's on the manufacturing CMC side. (Emphasis added).

51. The foregoing statements in the Prospectus, January 26, 2015 press release, Q4 2014 Earnings Call, and Q1 2015 Earnings Call regarding the Company's launch, including the timing and expected success, of Triferic were materially false and misleading because Defendants failed to disclose that they actually intended a (not-yet-approved) powder formulation of the drug to serve as the primary product offering for Triferic as it was more likely to be commercially viable given its lower cost to manufacture and transport and lower cost for end users, and that the powder form of the drug was subject to its own separate NDA that had not yet even been filed at the time the foregoing statements were made.

52. On June 25, 2015, unbeknownst to investors, the Company secretly submitted a separate NDA to the FDA to seek approval for Triferic in a powder packet formulation (the "2015 NDA"), which the Company intended to be the primary product offering for Triferic because it was more likely to be commercially viable given its lower cost to manufacture and transport and lower cost for end users.

53. On August 4, 2015, the Company held its second quarter 2015 financial results conference call (the "Q2 2015 Earnings Call") with securities analysts and investors. During the call, Defendant Chioini stated the following with regards to the commercial launch of Triferic:

> Before I get into the details of the quarter, I'd like to give you some insight on where we intend to go as a company. As a company we have achieved numerous important milestones over the past 20 years, and certainly over the past 18 months. ***Today as we approach commercialization, we are positioned to achieve great success with Triferic. As we have success with Triferic***, and take advantage of additional opportunities, we intend to build Rockwell into a leading dominant pharma company in the renal space.
>
> With that, I will highlight our Q2 financial results and then provide an update on our continued progress with Triferic and our preparations for the upcoming commercial launch. Sales in the quarter were $13 million, in line with what we reported in the second quarter last year. Gross profit continues to improve, we reported $2.1 million in gross profit, an increase of 2.3% year-over-year. At the end of June, cash and investments were over $77 million and we have no debt. ***Our strong financial position gives us ample resources to launch both of our drugs, Triferic and Calcitriol***. We continue to invest in API manufacturing, final product packaging, inventory, and marketing and sales.
>
> ***On our previous call, we stated that based on our prelaunch activity at that time, our commercial launch for Triferic and Calcitriol was estimated for the July-August timeframe. As of today, August 4th, I'm happy to tell you we remain on-track.*** (Emphasis added).

54. The foregoing statement in the Q2 2015 Earnings Call regarding the Company's launch, including the timing and expected success, of Triferic was materially false and misleading because Defendants failed to disclose that the yet-to-be-approved powder packet formulation of Triferic would be the primary product offering for Triferic as it was more likely to be commercially viable given its lower cost to manufacture and transport and lower cost for end users, and the powder form of the drug required a separate NDA.

55. On September 9, 2015, the Company issued a press release announcing the U.S. commercial launch of Triferic, stating in relevant part:

> WIXOM, Mich., Sept. 9, 2015 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (NASDAQ:RMTI), a fully-integrated biopharmaceutical company targeting end-stage renal disease

> (ESRD) and chronic kidney disease (CKD) with innovative products and services for the treatment of iron replacement, secondary hyperparathyroidism and hemodialysis, ***announced today the nationwide commercial availability of Triferic*** (ferric pyrophosphate citrate). Triferic is the only FDA approved iron product indicated to replace iron and maintain hemoglobin in hemodialysis patients in the United States.
>
> * * *
>
> "***We are thrilled to bring Triferic to the U.S. dialysis market***," stated Robert L. Chioini, Founder, Chairman and Chief Executive Officer of Rockwell Medical. "Triferic addresses a major unmet need as it overcomes functional iron deficiency in hemodialysis patients. IV iron is generally given weekly and by design is trapped in the patient's liver, which leads to iron overload and the functional iron deficiency that is prevalent in patients today. Triferic however replaces iron at every patient treatment and maintains hemoglobin concentration without increasing iron stores, because the iron is used immediately and not stored in the liver. Triferic benefits patients, nurses, doctors and healthcare providers and we are very motivated to commercialize it. ***We believe Triferic will become the standard of care in iron replacement for dialysis patients***." (Emphasis added).

56. The foregoing statements in the September 9, 2015 press release regarding the Company's launch, including the timing and expected success, of Triferic were materially false and misleading because Defendants failed to disclose that the yet-to-be-approved powder packet formulation of Triferic would be the primary product offering for Triferic as it was more likely to be commercially viable given its lower cost to manufacture and transport and lower cost for end users, and the powder form of the drug required separate FDA approval under its own NDA.

57. On November 9, 2015, the Company issued a press release announcing its third quarter fiscal year 2015 results. In the press release, Defendant Chioini touted the commercial launch of Triferic, stating in relevant part:

> "We experienced solid concentrate sales and results, and most importantly ***we commenced U.S. commercial launch of Triferic, our innovative iron replacement and hemoglobin maintenance***

> ***drug to treat anemia in hemodialysis patients. The clinical community has responded favorably to Triferic*** and its unique mechanism of action, which enables iron to bind immediately to transferrin and bypass the current iron sequestration and RE block that occurs with IV iron products. The drug's ability to deliver iron at every patient treatment and maintain hemoglobin concentration without increasing iron stores has received strong interest across the spectrum of dialysis providers, from large-to-small. ***We anticipate broad clinical adoption over the next several months of this first-in-class iron maintenance therapy for ESRD patients***." (Emphasis added).

58. On November 9, 2015, the Company held its Q3 2015 Earnings Call. During the Q3 2015 Earnings Call, Defendant Chioini touted the commercial launch of Triferic and the purported signing of a supply contract for Triferic with one of the largest dialysis providers, staining in part:

> Thank you, Mike, and good afternoon to everyone joining us on the call today. ***We made significant progress on a number of fronts during the third quarter. Most importantly, the U.S. commercial launch of Triferic***, and we're excited to provide this update. On the call today, I will review some of our accomplishments and then turn the call over to Tom, who will discuss the financials. After that both, Tom and I, and Dr. Pratt are available to take questions.
>
> Beginning with our financial results, our sales for the third quarter of 2015 were $14.4 million, up 4.6% over the comparable period in 2014. Gross profit was $2.5 million representing a 10.3% increase for the same period last year. We have a strong balance sheet. We ended September with approximately $73 million in cash and investments and we have no debt. ***In September, we announced commercial availability of Triferic***, and we're very excited that this important new drug is now available to dialysis patients.
>
> Just over the first eight weeks, Triferic has received positive feedback from the dialysis community including providers, doctors, nurses, and patient advocacy groups. And although expected it is very encouraging. ***Importantly, I'm pleased to announce that we have just signed a supply contract with one of the four largest dialysis providers. We have taken orders from other customers as well. We continue to be very busy promoting Triferic to our customer base.*** As you are aware, we know this market very well, having successfully launched a number of renal products over the

> past 20 years. We have stable long-term relationships with all the providers cultivated by providing them with innovative, high quality products and exceptional customer delivery service consistently overtime. And we are leveraging these relationships as we roll out Triferic.
>
> As you know this is a very concentrated customer market, and after two recently announced acquisitions there are now just seven customers who control about 85% of the market, all of whom we have relationships with. Due to the concentrated nature of our customer base, ***we expect Triferic to capture a significant portion of the market.*** Triferic as we announced previously was granted a unique product reimbursement code by CMS. Last week CMS came out with its final rules detailing how the agency will pay for services provided to Medicare beneficiaries for 2016. As expected, Triferic is in the bundled reimbursement, therefore as already accounted for in the bundled payment made to healthcare providers. So when the customers convert to Triferic, they will be paid for Triferic from the portion of their payment that was originally allocated to IV iron.
>
> We've talked a lot about Triferic and how it's a true iron maintenance therapy, its exceptional safety profile, it's unique mode of action, its ability to donate its iron directly to transparent and bypass the RE block resulting in efficient iron delivery and stable hemoglobin concentrations without increasing iron stores. The fact is, Triferic is the most important new treatment option for hemodialysis patients in the last 25 years. Triferic benefits all stakeholders within the healthcare system; patients, nurses, doctors, and healthcare providers. ***And we expect Triferic to become the standard of care in treating anemia and dialysis patients in the U.S., and then over the next several years globally.*** (Emphasis added).

59. The foregoing statements in the November 9, 2015 press release and Q3 2015 Earnings Call were materially false and misleading because Defendants failed to disclose that the yet-to-be-approved powder packet formulation of Triferic would be the primary product offering for Triferic because it was more likely to be commercially viable given its lower cost to manufacture and transport and lower cost for end users, and the powder form of the drug required separate FDA approval under its own NDA.

The Truth Emerges

60. On February 29, 2016, the Company issued a press release after the market closed announcing disappointing fourth quarter and fiscal year 2015 results. In the press release, Defendant Chioini revealed that the powder packet formulation of Triferic for the first time, stating in relevant part:

> "We had an exceptional year in 2015," stated Mr. Robert L. Chioini, Chairman and CEO of Rockwell. "We obtained FDA approval for Triferic, scaled-up manufacturing and launched our novel iron replacement drug in September. We have been educating customers large and small about Triferic's clinical and cost-saving benefits and its convenient in-center use. ***We have also strengthened the foundation for the drug's commercial success by developing new packaging, which provides economic benefit to our customers and Rockwell, and it should be commercially available in about 8 weeks. Importantly, we are working with CMS to obtain transitional add-on payment for Triferic which, if obtained, should have a positive impact on market adoption***. We expect Triferic sales to grow considerably in 2016. Additionally, in advancing our global licensing strategy, we recently secured what we believe to be the best positioned pharmaceutical partner in China to commercialize Triferic for both hemodialysis and future therapeutic indications, along with Calcitriol, in what will become the single largest dialysis market in the world." Mr. Chioini also stated, "We expect to have Calcitriol commercially available to customers in the U.S. near the end of April and we expect our product sales to start generating profits in 2016." (Emphasis added).

61. On February 29, 2016, the Company held its Q4 2015 Earnings Call with securities analysts and investors to discuss its disappointing fourth quarter and fiscal year 2015 results. During the Q4 2015 Earnings Call, Defendant Klema revealed that the commercial launch for Triferic was not successful, stating in part, "***Our net sales of Triferic were immaterial for 2015***." (Emphasis added).

62. During the Q4 2015 Earnings Call, Defendant Chioini revealed that the Company submitted a NDA to the FDA for approval of Triferic in a powder packet formulation and that this formulation would be primary product offering for Triferic, stating in relevant part:

Robert Chioini

While the normal sales process is occurring, we have been working on two key initiatives and both are important to commercial rollout. These are packaging and reimbursement. Regarding packaging, prior to submitting our NDA to the FDA, for Triferic drug approval, we created a more efficient and more cost-effective way to package Triferic.

Instead of having the active pharmaceutical ingredient or API manufactured as a powder and packaged into a liquid solution in an ampoule, which is what was FDA approved, we determined we could take the manufactured API powder straight to finished packaging, with an additional process step in between. So we are able to package Triferic as a powder in a packet, similar to a packet of sugar.

This improvement enables the customer to reduce the storage space and number of orders needed to utilize the drug, and it greatly reduces Rockwell's cost of goods compared to the liquid ampoule. ***This required a separate NDA and we filed that submission with the FDA last year, and we expect to have approval by the end of April. The powder packet will be commercially available immediately thereafter, and it will be the primary product offering.*** (Emphasis added).

63. During Q4 2015 Earnings Call, Defendants Chioini had the following exchange with a securities analyst regarding the initial commercial launch of Triferic and the powder packet formulation of Triferic:

Annabel Samimy

I just want to understand something. ***If I heard you correctly, you're not really going to be launching Triferic, until you get approval of this powder, this new packaging,*** and it doesn't seem like you have any kind of agreement on reimbursement from CMS, so for this x bundle type of reimbursement, so are you also not going to be able to price Triferic, until you have agreement with CMS, because this is already a year plus after launch***, and I guess, I'm little bit surprised that you can't seem to launch this product at all?***

Robert Chioini

> So I'd spread off and I'd say, we launched the product in September. And at that time, the clarity that we had on the reimbursement was the bundle. And then in November after CMS -- CMS was in a quiet period up till November, it became clear that we have an opportunity to secure a different type of reimbursement, which I explained on the call, was transitional. So the drug was launched.
>
> As far as the packaging goes, the ampules are what are being used currently. The ampules will continue to be used until the powder packet is available. I'm limited on what I can share in terms of pricing, as we're in the midst of being in discussions with CMS on this transitional payment.
>
> I mentioned on the call that there's no formal process, there is nothing where you submit. You have to wait x number of days. It's a fluid process and we're working on it as we speak. So we continue to do the work with customers both large and small. And at the same time, we continue to do the work on reimbursement. It's obviously important to have that reimbursement squared away sooner than later. (Emphasis added).

64. On this news, shares of Rockwell Medical fell $3.29 per share or approximately 34% from its previous closing price to close at $6.31 per share on March 1, 2016, damaging investors.

65. On March 1, 2016, analysts reacted to the Company's earnings announcement and call. For example, analyst Charles Haff of Craig-Hallum Capital Group, LLC wrote:

> We expect the stock to be significantly weak today (traded below $7 after hours) because management announced that they are changing their Triferic commercialization strategy. Previously, they expected their form factor for the drug to be sold in ampules which dialysis clinics would mix into their dialysate solutions and now they have filed for a new NDA with FDA to ask for approval of a powder form. ***Management claims they pursued this strategy to improve their COGS and shipping costs***. (Emphasis added).

66. According to Morgan Stanley analysts Andrew Berens and Thomas Smith:

> Yesterday, after market close, Rockwell reported Q4 2015 earnings. Notably absent from the call was any discussion of Triferic sales 14-months post approval, which were disclosed in the 10-K filing to be $0.2mn for full year 2015. The call was also devoid of any mention

> of ongoing pilot studies or contract negotiations, both of which were highlighted during the Q2 and Q3 2015 earnings calls and served as significant RMTI catalysts. We find the lack of material sales and commercial progress very concerning, making us question whether the drug has found any demand in the marketplace from the chain providers, which may explain the recent announcement that the company is targeting an orphan indication (IRIDA) with the drug. Given the paucity of interest from providers and the lack of ongoing pilot studies, we are significantly reducing our Triferic sales by two thirds, and now model $32mn peak sales (vs previous $95mn). ***We have not changed our pricing assumptions for the Triferic, but believe that the company may have to resort to a significantly altered pricing strategy to stimulate demand***. We think investors will be equally disillusioned from the call, lack of commercial progress and inability to produce any material revenues, significantly pressuring RMTI shares without much to offset the downward trend. (Emphasis added).

67. Thus, analysts understood that pricing was critical to the commercialization of Triferic and that the liquid version did not allow the Company to sell the drug at a price that would spur demand and, in turn, profitability.

68. On April 6, 2016, *The Motley Fool* published an article on the Company, which revealed that the supply contract for Triferic with one of the largest dialysis provider disclosed during the Q3 2015 Earing Call was in fact a contract for a pilot program, stating in part:

> ***In November, CEO Rob Chioini stated that the company had signed a supply contract with one of the largest dialysis providers.*** Was Triferic about to take off? Nope. Rockwell Medical's revenue during the fourth quarter decreased slightly compared to the prior-year period. CFO Thomas Klema admitted that "net sales of Triferic were immaterial for 2015." ***The supply contract referred to by Chioini turned out to be for some type of pilot program.*** The large dialysis provider remains anonymous. (Emphasis added).

69. Confirming that Defendants' disclosure concerning a supply contract for the sale of Triferic was a false claim designed to mislead about their prospects for commercializing Triferic, Morgan Stanley's Berens and Smith on May 11, 2016 wrote:

> **No discussion of new pilot studies or additional contract wins.** Rockwell did not mention the onset of any Triferic pilot studies or additional contracts, confirming lackluster demand for the drug in its current formulation and with the existing reimbursement dynamics. As a reminder, management previously highlighted ongoing pilot studies (Q2 2015 call) and a supply contract (Q3 2015 call) with a top 4 dialysis provider, ***so the lack of clarity on these items is concerning***, especially in light of the comments in the 10-Q suggesting not to expect "significant" Triferic revenues without pass-through status determination. (Emphasis added).

70. Even after achieving FDA approval for Triferic in the powder form, the Company posted no material sales of Triferic. As Morgan Stanley's Berens and Smith noted in an August 9, 2016 report:

> **Rockwell 2Q16 earnings missed top and bottom line consensus, in another quarter absent meaningful Triferic revenues.** Rockwell reported total revenues of $13.5mn in Q2, 3% below consensus of $13.9mn. Rockwell did not specifically disclose sales of Triferic in the quarterly earnings release, but has noted in its 1Q16 Form 10-Q that "*Until we obtain transitional add-on reimbursement, or until we cease trying to obtain it, we expect Triferic sales activity to not be significant*," suggesting that the company deems an exclusion from the bundled dialysis payment as critical for Triferic success. Rockwell also missed expectations on the bottom line, posting a net loss of ($0.11) per share, vs. consensus loss per share of ($0.10). (Emphasis in original).

71. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

72. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Rockwell Medical securities trade on NASDAQ during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the

Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

73. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Rockwell Medical securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Rockwell Medical or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

74. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

75. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

76. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;

- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Rockwell Medical;
- whether the Individual Defendants caused Rockwell Medical to issue false and misleading public statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading public statements;
- whether the prices of Rockwell Medical securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and,
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

77. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

78. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Rockwell Medical securities are traded in efficient markets;

- the Company's common stock were liquid and traded with moderate to heavy volume during the Class Period;
- the Company's common stock traded on NASDAQ Global Market, a highly efficient and automated market;
- as a regulated issuer, the Company filed periodic public reports with the SEC;
- During the class period, on average, over 3.3 million shares of the Company's common stock were traded on a weekly basis, representing approximately 7.02% of the total float of 47.35 million shares or approximately 6.45% of the 51.53 million shares outstanding, demonstrating a very active and broad market for the Company's common stock and permitting a very strong presumption of an efficient market;
- the Company was covered by at least five securities analysts employed by a major brokerage firm, including Craig-Hallum, Bank of America Merrill Lynch, LifeSci Advisors, Oppenheimer, and Stifel;
- the price of the Company's common stock rapidly reflected new, Company-specific information; and
- numerous FINRA member firms were active market-makers in the Company's common stock at all times during the Class Period.

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiffs and members of the Class purchased and/or sold Rockwell Medical securities between the time the Defendants failed to disclose or misrepresented

material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

79. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

80. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

NO SAFE HARBOR

81. The Company's "Safe Harbor" warnings accompanying its reportedly forward looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability. To the extent that projected revenues and earnings were included in the Company's financial reports prepared in accordance with GAAP, they are excluded from the protection of the statutory Safe Harbor. *See* 15 U.S.C. §78u-5(b)(2)(A).

82. Defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of the Company who knew that the FLS was false. None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

COUNT I

Violation of Section 10(b) of the Exchange Act and Rule 10b-5 against All Defendants

83. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

84. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

85. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiffs and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Rockwell Medical securities; and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise acquire Rockwell Medical securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

86. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to

influence the market for Rockwell Medical securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Rockwell Medical's finances and business prospects.

87. By virtue of their positions at Rockwell Medical, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

88. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Rockwell Medical, the Individual Defendants had knowledge of the details of Rockwell Medical's internal affairs.

89. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Rockwell Medical. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Rockwell Medical's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public

statements, the market price for Rockwell Medical's securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Rockwell Medical's business and financial condition which were concealed by Defendants, Plaintiffs and the other members of the Class purchased or otherwise acquired Rockwell Medical securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged upon the revelation of the alleged corrective disclosures.

90. During the Class Period, Rockwell Medical's securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Rockwell Medical securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and the Class, the true value of Rockwell Medical securities was substantially lower than the prices paid by Plaintiffs and the other members of the Class. The market price of Rockwell Medical's securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

91. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

92. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

Violation of Section 20(a) of the Exchange Act against the Individual Defendants

93. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

94. During the Class Period, the Individual Defendants participated in the operation and management of Rockwell Medical, and conducted and participated, directly and indirectly, in the conduct of Rockwell Medical's business affairs. Because of their senior positions, they knew the adverse non-public information regarding Rockwell Medical's business practices.

95. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Rockwell Medical's financial condition and results of operations, and to correct promptly any public statements issued by Rockwell Medical which had become materially false or misleading.

96. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Rockwell Medical disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Rockwell Medical to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Rockwell Medical within the meaning of

Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Rockwell Medical securities.

97. Each of the Individual Defendants, therefore, acted as a controlling person of Rockwell Medical. By reason of their senior management positions and/or being directors of Rockwell Medical, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Rockwell Medical to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Rockwell Medical and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

98. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Rockwell Medical.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

Dated: November 21, 2016

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

By: /s/ *Kevin Chan*
Phillip Kim, Esq. (PK 9384)
Laurence M. Rosen, Esq. (LR 5733)
Kevin Chan (KC 0228)
275 Madison Avenue, 34th Floor
New York, NY 10016
Phone: (212) 686-1060
Fax: (212) 202-3827

and

Jacob A. Goldberg
101 Greenwood Avenue, Suite 440
Jenkintown, PA 19046
Phone: (215-600-2817
Fax: (212) 202-3827

GLANCY PRONGAY & MURRAY LLP
Lesley F. Portnoy (LP-1941)
122 East 42nd Street, Suite 2920
New York, New York 10168
Telephone: (212) 682-5340
Facsimile: (212) 884-0988

and

Lionel Z. Glancy
Robert V. Prongay
Kara M. Wolke
1925 Century Park East, Suite 2100
Los Angeles, CA 90067
Telephone: (310) 201-9150
Facsimile: (310) 201-9160

Lead Counsel for Lead Plaintiffs and the Class

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document, filed through the ECF system on November 21, 2016, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ *Kevin Chan*
Kevin Chan